

Remarks

Claims 1 and 8-12 are pending in the application. Claims 1, 9, and 12 have been amended to correct a spelling error as requested by the Examiner.

Response to Rejections under 35 U.S.C. § 112¶2

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112¶2 based on the Examiner's contention that they are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner contends that the phrase 'radionuclide being associated with a targeting moiety' renders the claims indefinite because it is not clear how the radionuclide is associated with the targeting moiety. The Applicants respectfully traverse this rejection.

Page 7, line 11, through page 9, line 6, of the specification describes how the radionuclide may be placed in spatial proximity with the targeting moiety. The various ways include a covalent or non-covalent chemical bond, incorporation of the targeting moiety and radionuclide into a confined area such as a liposome, attaching both the targeting moiety and radionuclide to a matrix, and attaching the radionuclide to the targeting moiety through a chelating structure. Given the varied ways the radionuclide may be in spatial proximity to the targeting moiety, the phrase "associated with" is the best way to convey meaning and proper breadth, (i.e. to say "bonded with" would exclude those cases, for example, where the radionuclide and targeting moiety are within a liposome). Please note that the examples cited here and stated in the specification are not meant to read limitations into the claims, but rather are to show that one of ordinary skill in the art would understand what is meant by "associated with" and would know the metes and bounds of the claims

Accordingly, the Applicants respectfully request the withdrawal of the rejections based on 35 U.S.C. § 112¶2.

Response to Rejections under 35 U.S.C. § 103(a)

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 103(a) based on the

Examiner's contention that they are obvious over Calenoff (U.S. Patent No. 6,025,477) in view of Conti et al. (U.S. Patent No. 6,331,287) and further in view of Fritzberg et al. (U.S. Patent No. 5,175,343). The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a cardiovascular imaging agent comprising a radionuclide associated with a targeting moiety wherein the targeting moiety is selected from the 7 possible types of targeting moieties expressed in independent claims 1, 9 and 12. The Applicants respectfully traverse this rejection.

Calenoff discloses antigens the presence of which are indicative of atherosclerotic plaque. Calenoff discloses radioimaging atherosclerotic plaque using an antibody which specifically binds to an atherosclerotic plaque specific antigen. Therefore, in Calenoff, the targeting moiety is an antibody. See column 2, lines 48-53, column 3, lines 18-21 and lines 65-66, and column 8, lines 11-17. Examples of antibodies include those listed in column 7 of Calenoff.

Independent claims 1, 9, and 12 list the possible targeting moieties as (i) cells, including muscle cells, macrophages, foam cells, monocytes, polymorphonuclear cells, cellular fragments and analogs thereof, (ii) colony stimulating factors, and platele factor 4, (iii) growth factors, (iv) cytokines, interferons, and tumor necrosis factors, (v) cellular sources of energy for metabollic active plaque formation, (vi) lipids and lipid receptors, and (vii) component of clotting cascades. This list does not include antibodies. Antibodies are plasma proteins that bind specifically to antigens. The 7 categories of targeting moieties listed above do not bind to antigens. Given that it is known in the art that antibodies bind specifically to antigens, it would not be obvious from Calenoff to use other types of targeting moieties because there would be no expectation of success. This is especially true for the targeting moieties listed in independent claims 1, 9, and 12 which are not known to bind antigens.

Conti et al. was cited by the Examiner only for its teachings that ¹⁸F is a label for PET imaging. Therefore, Conti et al. does not make up for Calenoff's deficiency of not teaching the targeting moieties of independent claims 1, 9, and 12.

Fritzberg et al. was cited by the Examiner for its teaching of the importance of generating a kit. Therefore, Fritzberg et al. also does not make up for Calenoff's deficiency of not teaching the targeting moieties of independent claims 1, 9, and 12.

Because it would not be obvious to prepare a cardiovascular imaging agent where the targeting moiety is selected from the list contained in independent claims 1, 9, and 12 in view of the cited references, either individually or in combination, the Applicants respectfully submit that the inventions as claimed are novel and non-obvious over the prior art.

Accordingly, the Applicants respectfully request the withdrawal of the rejections based on 35 U.S.C. § 103(a).

Comments/Notes

The Examiner has requested the Applicants to correct the spelling of platelet in independent claims 1, 9, and 12. The Applicants have amended the claims accordingly.

Fees

The Applicants believe they have provided for the required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any additional required fee to our Deposit Account, **06-1448**.

Conclusion

For the foregoing reasons, the Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the pending claims are now in condition for allowance and early notification to this effect is earnestly solicited. If any questions are raised by this Amendment and Response, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,
Patent Group
Foley Hoag LLP

By: Michael J. DiVerdi
Michael J. DiVerdi, PhD
Reg. No. 51,620
Agent for Applicants

155 Seaport Boulevard
Boston, MA 02210
Telephone: (617) 832-1000
Telecopier: (617) 832-7000

Date: 7/19/04